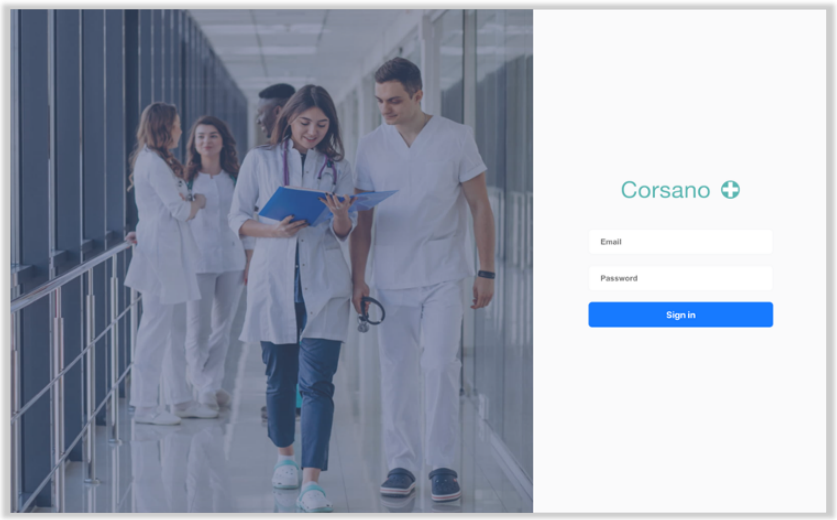
EN



CardioWatch 287 System

Study Portal Instruction Manual

Corsano Health B.V.
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CE 1912

List of Abbreviations

Abbreviation	Abbreviation Meaning
A-V	Arterio-venous
ECG	Electrocardiogram
EMC	Electromagnetic Compatibility
FCC	Federal Communications Commission
HF	High Frequency
ICU	Intensive Care Unit
ISED	Innovation, Science and Economic Development Canada
LED	Light Emitting Diode
MRI	Magnetic Resonance Image
RF	Radiofrequency
RPM	Respirations per Minute
RSS	Radio Standards Specifications
SpO2	Functional oxygen saturation
USB	Universal Serial Bus
WEEE	Waste Electrical and Electronic Equipment

⚠ **WARNING:** A WARNING statement provides information about a potentially hazardous situation which, if not avoided, could result in serious injury or damage.

⚠ **CAUTION:** A CAUTION statement provides information about a potentially hazardous situation which, if not avoided, may result in injury to the user or subject, or in damage to the equipment or other property.

In the United States, this product is for Investigational Use Only.

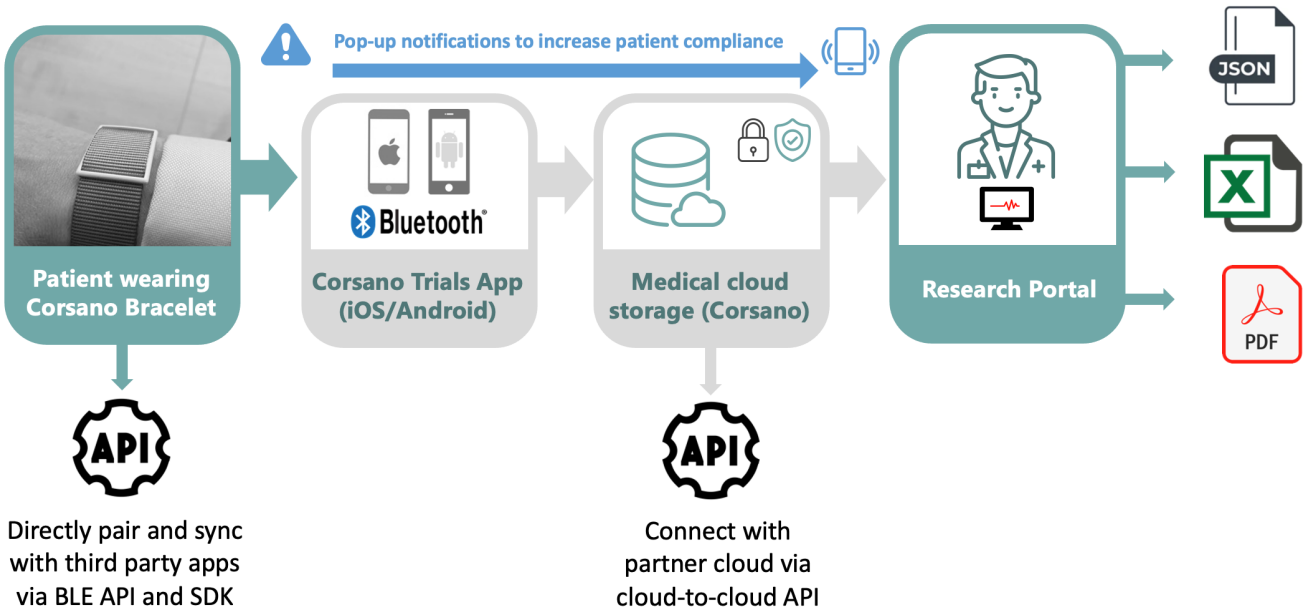
1. TABLE OF CONTENTS

2. INTRODUCTION

The Corsano CardioWatch 287 System is a vital signs monitoring system that consists of a monitoring bracelet device worn on the wrist by adults (aged 18 years old and over), a user mobile application, a secure cloud and a web-based browser platform.

Vital signs data both on mobile devices and web-based dashboard are available to the researcher and subject based on Study Settings.

The following figure shows the Corsano CardioWatch 287 System for studies:



CardioWatch 287 System

The bracelet is intended to continuously monitor physiological vital sign data from the person being monitored and securely transmit the encrypted data via the Corsano App to the secure server.

The bracelet is intended for use in professional healthcare facilities, such as hospitals or skilled nursing facilities, or the home by trained healthcare professionals.

The Corsano CardioWatch 287 System is also integrated with third-party devices for displaying and monitoring physiological signs (spot monitoring of: non-invasive blood pressure, lung function & spirometry, weight as well as continuous monitoring of axillary temperature.

This Instructions for Use Manual is for the Study Portal only. Please contact Corsano for instructions for the Web Portal for typical Remote Patient Monitoring (RPM) and In-Hospital monitoring.

These Instructions for Use assume a working knowledge of vital signs monitoring.
To support proper, safe, and accurate operation of the CardioWatch 287 System, read all operating instructions carefully before you use the system.

3. SAFETY INSTRUCTIONS

This instruction manual provides you with important information about the Corsano Study Portal. To ensure the safe and proper use of the CardioWatch 287 System, READ and UNDERSTAND all of the safety and operating instructions. If you do not understand these instructions or have any questions, contact support@corsano.com before attempting to use this device.

3.1. WARNINGS

⚠ To maintain subject safety, adhere to all WARNINGS and CAUTIONS listed in these Instructions for Use.

⚠ The CardioWatch 287 System is intended for use by qualified medical personnel only; USA Federal Law restricts this device to sale by or on prescription of a Physician.

⚠ The CardioWatch 287 System is not intended for use in high-acuity environments, such as an ICU or operating rooms.

⚠ The CardioWatch 287 System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias, e.g., very fast atrial fibrillation. For these patients, continuous ECG monitor should be used. The CardioWatch 287 System is not a substitute for an ECG monitor.

⚠ The CardioWatch 287 System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.

⚠ Consult with the Physician before using this system for a patient that has common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. Any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement made by this device.

⚠ The physiological parameters and alarms displayed on the Study Portal are for Healthcare Practitioners reference only and cannot be directly used as the basis for clinical treatment. NEVER diagnose or treat the patient solely based on the patient's readings.

⚠ DO NOT adjust medication based on readings from this system. The patient should take medication as prescribed by the patient's Physician. ONLY a Physician is qualified to diagnose and treat illness of the patient. ALWAYS consult with the patient's Physician.

⚠ If any value displayed on the Study Portal is abnormal or questionable, first determine the patient's vital signs by alternative means and then verify that Study Portal is working correctly.

⚠ The device is not an apnea monitor. DO NOT rely on the respiration monitoring for detection of cessation of breathing.

3.2. CAUTIONS

⚠ The computer running the Study Portal software must utilize an emergency power system. Failure to do so will result in loss of monitoring during extended periods of power failure. Hospitals without an emergency power system should use an Uninterruptible Power Supply (UPS) to power the computer running the Study Portal software. When there is a power failure, the system should be shut down by following the specified shutdown procedure before the UPS is turned off. If the system has a sudden power failure, system failure may occur and consequently the system will not work correctly next time.

⚠ Patients at risk for respiratory crises should be observed closely.

⚠ Movement, ambient light, and low perfusion may affect SpO2 and pulse rate calculation and accuracy. Corsano Health B.V. is not intended for use in calculating accurate SpO2 during periods of high motion, high ambient light, and low perfusion conditions.

⚠ SpO2 measurements are particularly sensitive to the pulsations in the artery and the arteriole. Measurements may not be accurate if the patient is experiencing shock, hypothermia, anemia or has received certain medications that reduce the blood flow in the arteries.

3.3. NOTES

⚠ Keep this manual in the vicinity of the computer running the Study Portal software so that it can be easily located when needed.

⚠ During normal use, the operator is expected to face the front of the equipment.

3.4. Indications for Use

The CardioWatch 287 System is a wireless remote monitoring intended for continuous collection of physiological data in home and healthcare settings. This includes heart rate, heart rate variability (R-R interval), SpO2, temperature, respiration rate, activity and sleep. Data is transmitted wirelessly from the device via the application or gateway to a server or health cloud where it is stored and made available for further analysis.

The CardioWatch 287 System can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The CardioWatch 287 System is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information.

The data from the CardioWatch 287 System is intended to be integrated in medical devices as an aid to diagnosis and treatment. It is not intended for use on critical care patients nor replace standard monitoring and/or routine care.

The CardioWatch 287 System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The CardioWatch 287 System is not a substitute for an ECG monitor.

The CardioWatch 28**7** System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.

3.5. Clinical Benefit

The CardioWatch 287 System provides a non-invasive, comfortable continuous and accurate monitoring of vital signs. Data is synched to the Corsano Study Portal where it is reviewed by healthcare professionals.

4. SYMBOLS

These instructions for use contain the following symbols (color and size may vary):

Symbol	Meaning
CE 1912	This product is a medical device classified as risk category IIa, in accordance with rule 10 of EU Directive 93/42/EEC, last amended by 2007/47/EC of the European Parliament and Council of 5 September 2007.
	Indicates the medical device manufacturer
	Indicates the need for the user to consult the instructions for use for important information such as warnings and cautions. A warning is always related to safety.
	Note Indicates the need for the user to consult the instructions for use
	Applied Part TYPE BF Applied Part (IEC 60417-5333)
REF	Indicates the manufacturer's reference so the medical device can be identified
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified
CE	CE marking indicates that a product complies with applicable European Union regulations
FC	FCC marking indicates the electronic device, which sold in the United States, is certified and the electromagnetic interference from the device is under the limits that are approved by Federal Communications Commission
	Indicates a product should not be disposed of in a landfill; the black bar indicates that the equipment was manufactured after 2005
	Refer to instruction manual/booklet.
	The wearable device does not generate alarms.

5. STUDY PORTAL

The Corsano Study Portal enables the PI to manage the data monitoring of their subjects.

Via a Web Browser, the PI configures the data to be monitored and visualize the list of subjects and vital parameters (Pulse rate, SpO2, temperature, respiration rate, movement) obtained from data originating from the Corsano Bracelet.

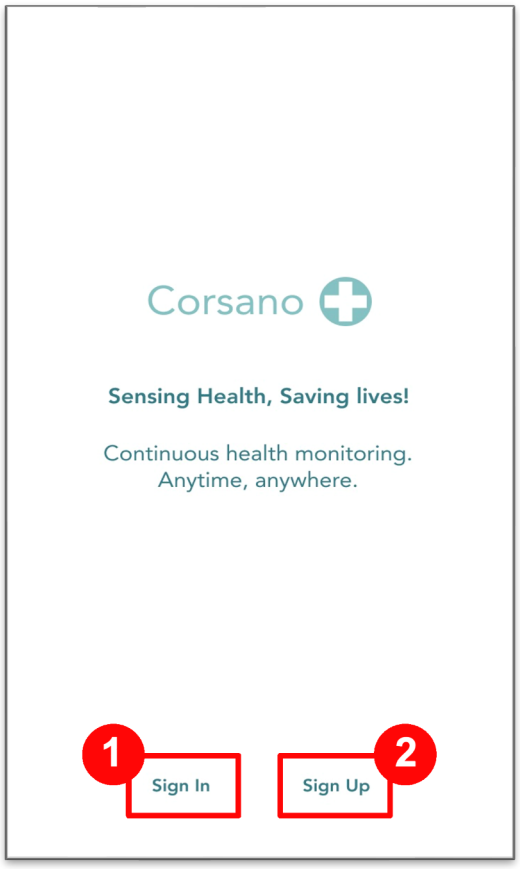
Parameters measured by compatible 3rd Party medical devices (Non-invasive blood pressure, lung function & spirometry, weight, axillary temperature) are displayed also on the Corsano Study Portal.

5.1. Sign-Up

You will first need to sign-up via the Corsano App. Please download and install the Corsano App onto your smart device.

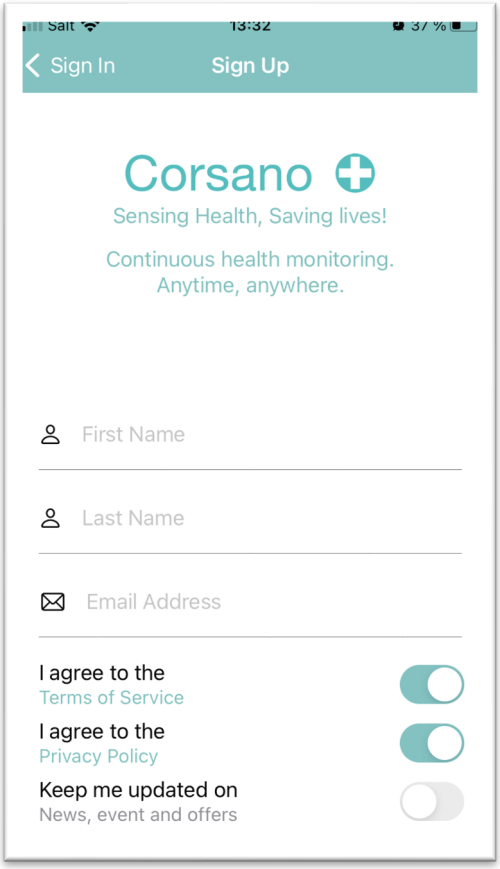
Download on the App Store GET IT ON Google Play

Select “Sign Up” to create a user account (2)



Choose Sign-Up

Enter First Name, Last name, Email



Sign-Up

Agree on Terms of Service and Privacy Policy

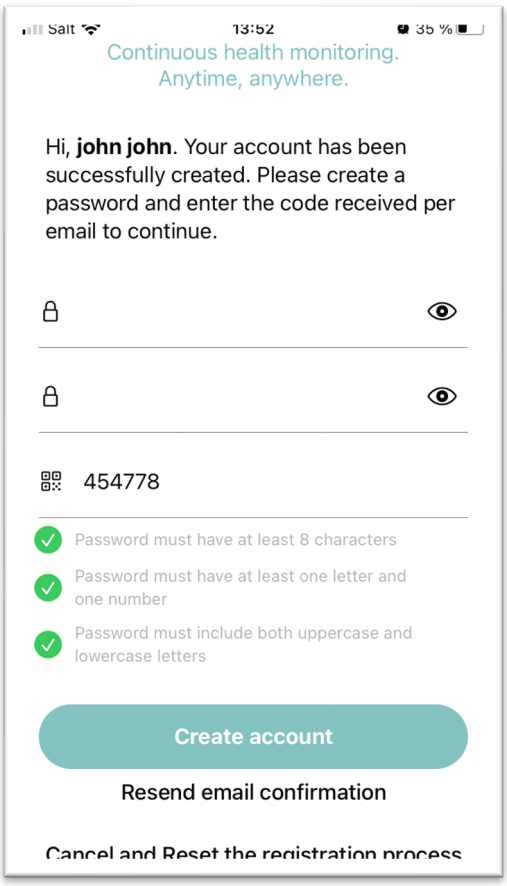
An email is sent to you with a 6-digit code.

Enter:

- Your password
- Your password again
- The received code

Press “Create account”

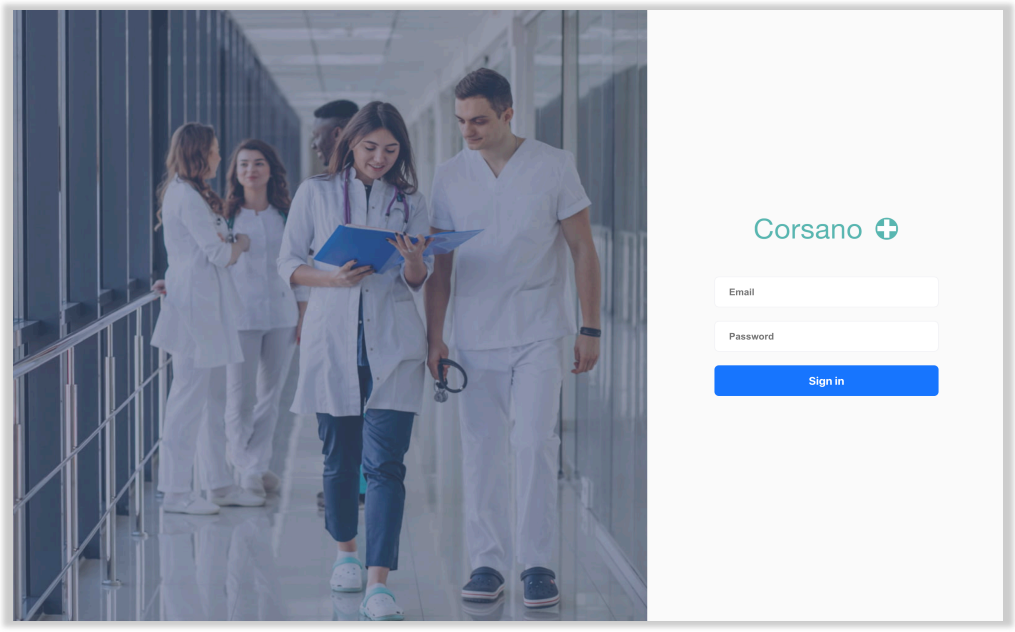
The password you use during registration is encrypted and will be known to you only (Corsano will not have it).



Create account

5.2. Sign-In

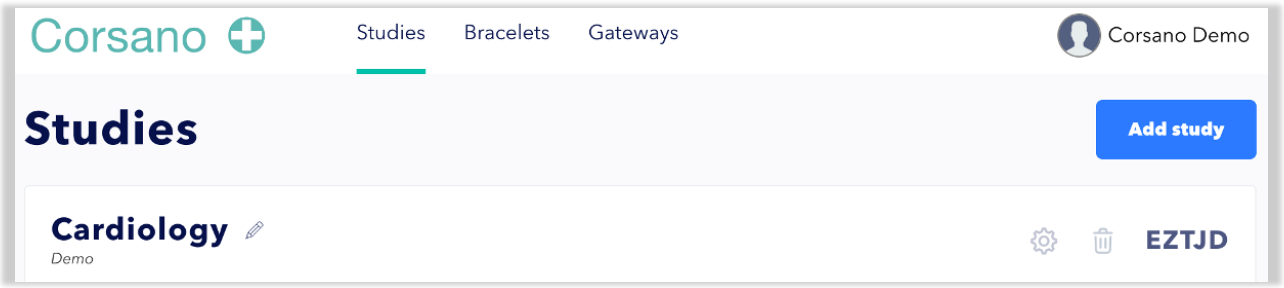
After registration via the Corsano App, you can sign-in with your email address and password to the Corsano Study Portal at http://study.corsano.com.



Sign-in Study Portal

5.3. Studies Dashboard

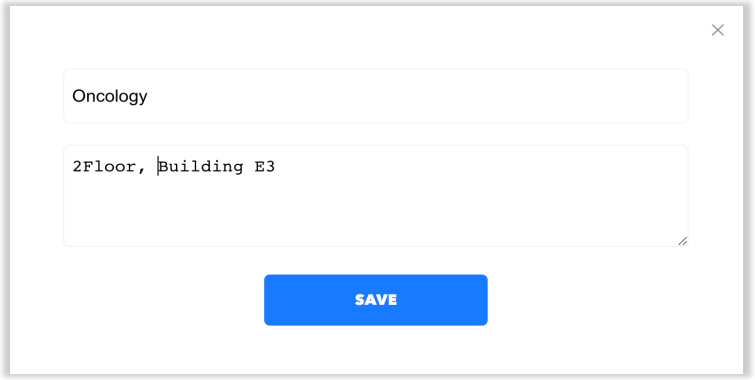
The Studies Dashboard is the homepage of the Corsano Study Portal. You can select the relevant study.



Studies Dashboard

5.4. Add Study

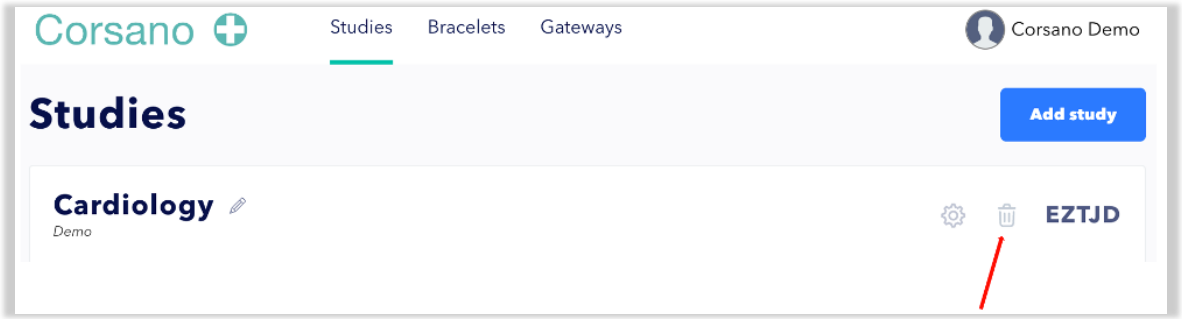
If no department has been setup on the Department Dashboard, or you want to add a new department, please click on the [ADD STUDY] button top right. You can type the name of the department and a description, then click [Save].



Add Study

5.5. Delete Study

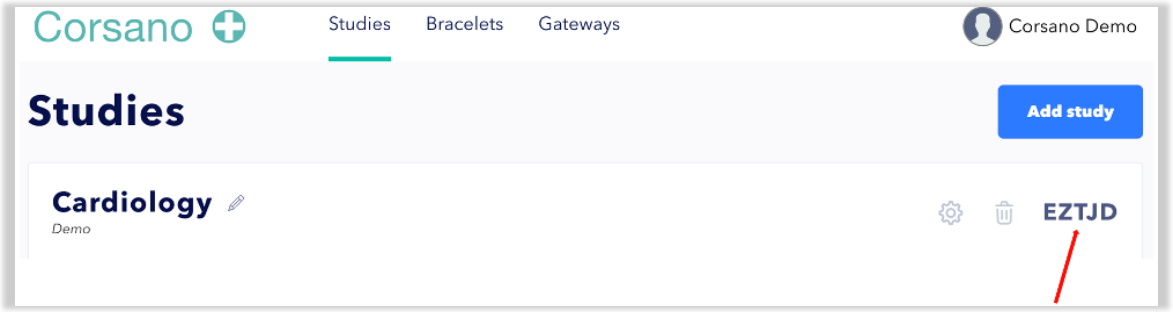
A Study can be deleted by clicking on the icon. To avoid that a study is accidentally deleted, you will need to confirm deletion.



Delete Study

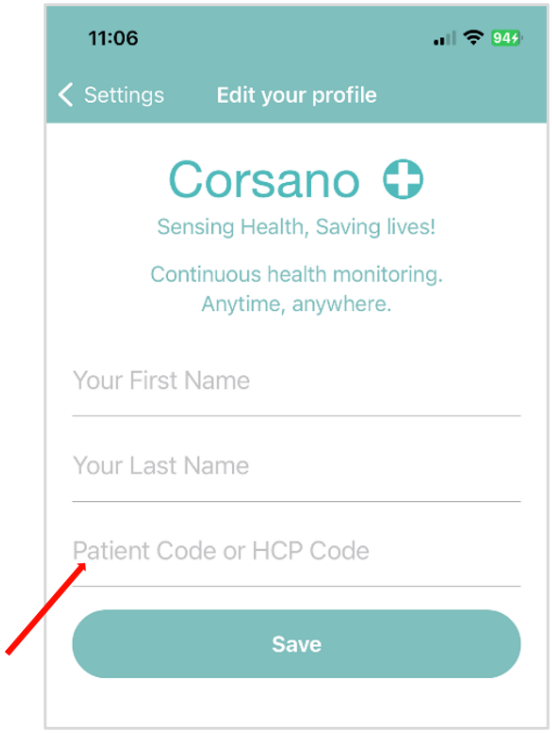
5.6. Assign Subjects

See the Study Code on right side, i.e. **EZTJD** in the above example. To include subjects in a study, please ask the subject to add the Study Code in their Corsano App under Settings/Profile.



Department Dashboard

On the Profile page under Settings in the Corsano App, the Subject is requested to enter the Study Code in the Code Field:



Add Study Code in Corsano App on Subjects mobile device

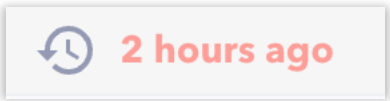
5.7. Subjects Overview

Click on a study to see an overview of subjects that are assigned to the study.

Subjects Overview

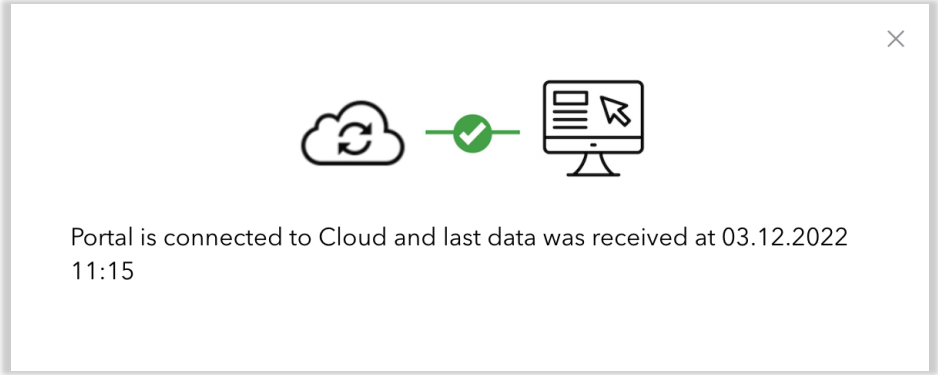
The screen gives the PI a general overview of the study subjects and their status.

Last Update – displays how long-ago subject data was received on the portal. If last data was received more that 5 min ago, number of minutes will be displayed in red.



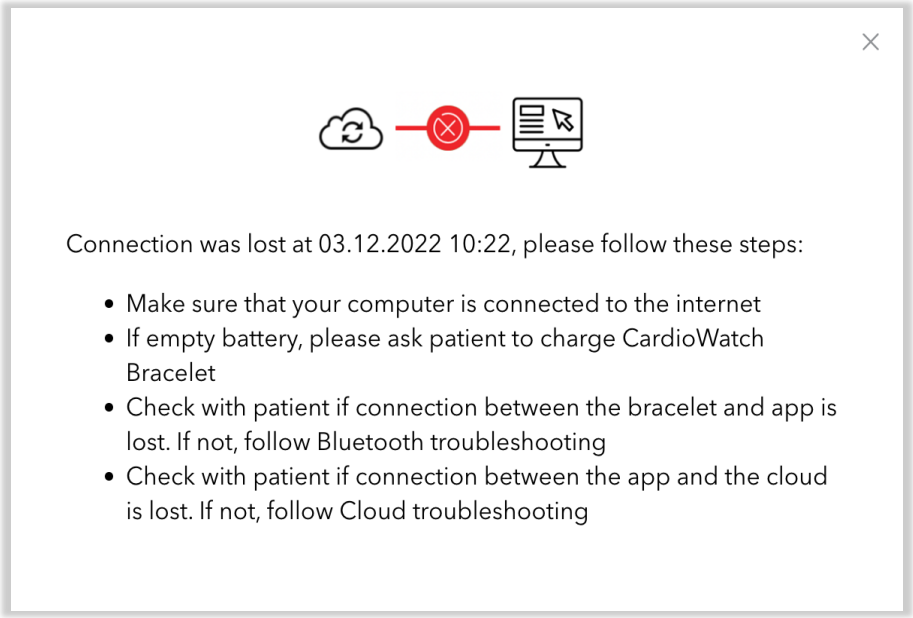
This could be due to several reasons, such as an issue with the device, the connection to the App, connection between the App and the Cloud or connection between the Study Portal and the Cloud.

Click on the Last Update icon to see connection status. If connection is good, you will see:



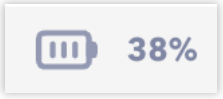
Portal is connected and receiving data

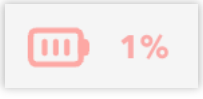
If connection is lost you will see:



Connection Troubleshooting

Batteries – displays the remaining battery for Corsano Bracelets. Low battery levels (under 20% left) will have a yellow battery icon. Under 10% the battery icon will turn red and under 5% it will start blinking.





If battery is empty the system will display an alarm on the Dashboard:
Low battery. Charge device

Vital Parameters

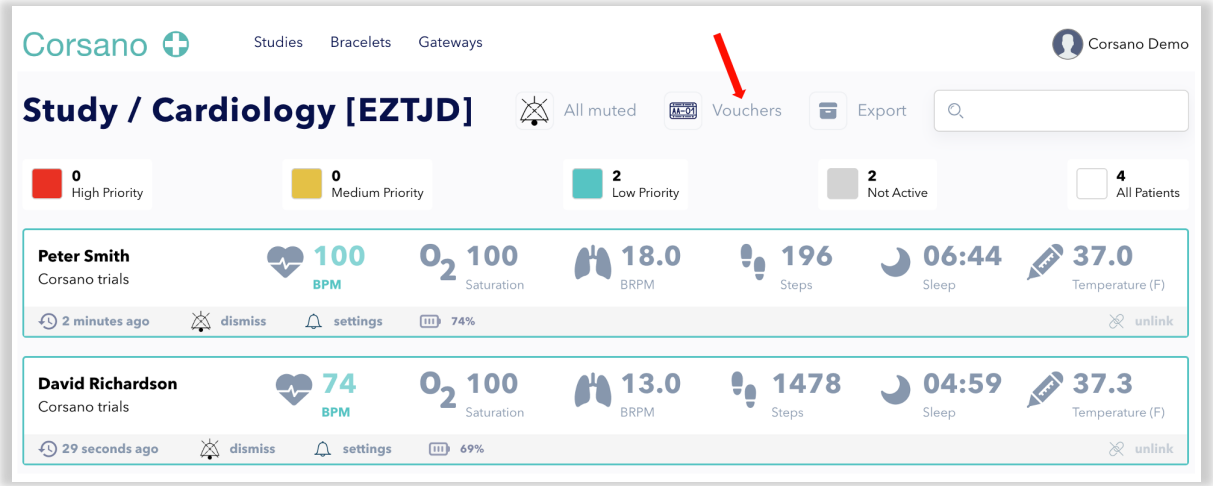
The Subjects Overview shows five vital parameters for each subject. The parameters presented are:

- Pulse Rate (PR, bpm)
- Blood oxygen saturation (SPO2, %)
- Respiratory Rate (RR, brpm)
- Motion (Steps for day)
- Temperature (°C/°F)

Subject Lookup – on the top right of the dashboard. Enables the search of a specific subject. Once selected, a list of all subjects in the study will appear. You can look up a subject by name or voucher code.

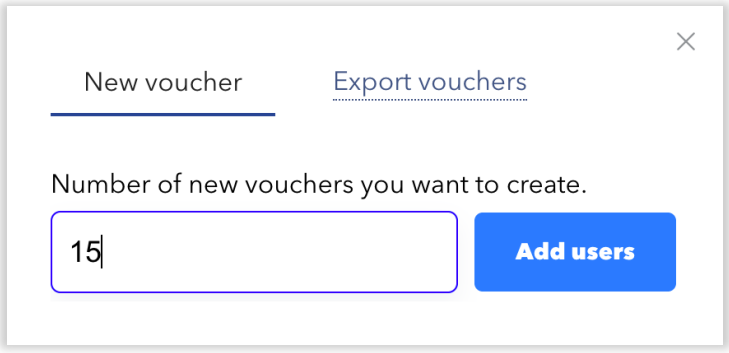
5.8. Vouchers

On the top middle of the dashboard. You can create voucher codes to de-identify subjects. Health data for each subject is saved under the voucher assigned to that subject. To add new voucher codes in the study you need to click on button “Vouchers”.



Create Vouchers to De-Identify Patients

Then please provide number of vouchers you want to create.

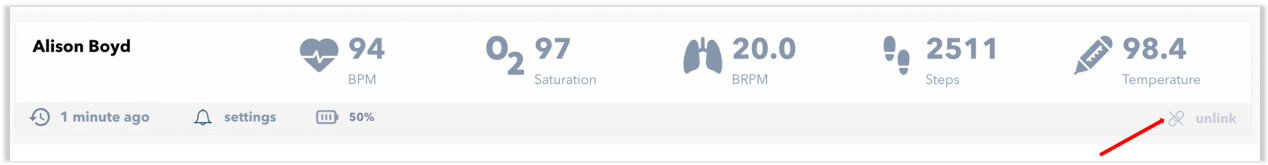


Type Number of Vouchers you want to create

Please click on the [ADD USERS] button to confirm the number of vouchers you want to create. The system creates new patients with unique voucher codes. These voucher codes are then used instead of emails when patients Sign-In in the Corsano App.

5.9. Un-assign Subject

This function is used to un-assign a subject from the overview, for example, when a subject is discharged. Click on the Unlink icon and select confirm on the pop-up message.



Remove subject from Subject Overview

NOTE: Once a subject is removed, their history and measurements will no longer be available on the Subjects Overview. All data will still be saved in the Corsano Cloud.

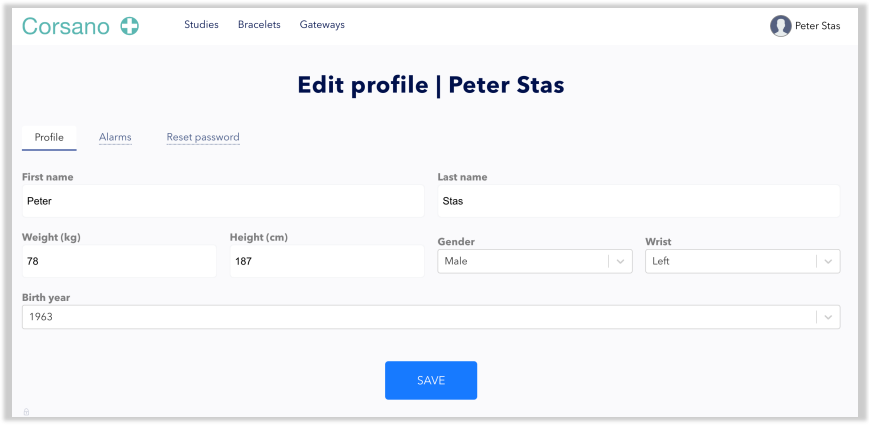
5.10. Subject Portfolio

A click on a subject on the Subjects Overview opens the detail page for that subject. The Subject Portfolio presents the subject's information and allows access to the subject graphs per vital parameter.

Subject Portfolio

Compliance – displays percentage of day for which data was received for the subject.

Edit Profile – the Personal Information is where subjects' demographics are listed. To edit a subject's personal information, click the [EDIT PROFILE] button on the top right of the section in the Subject Portfolio and edit Name, Gender, Year of Birth, Weight, Height.



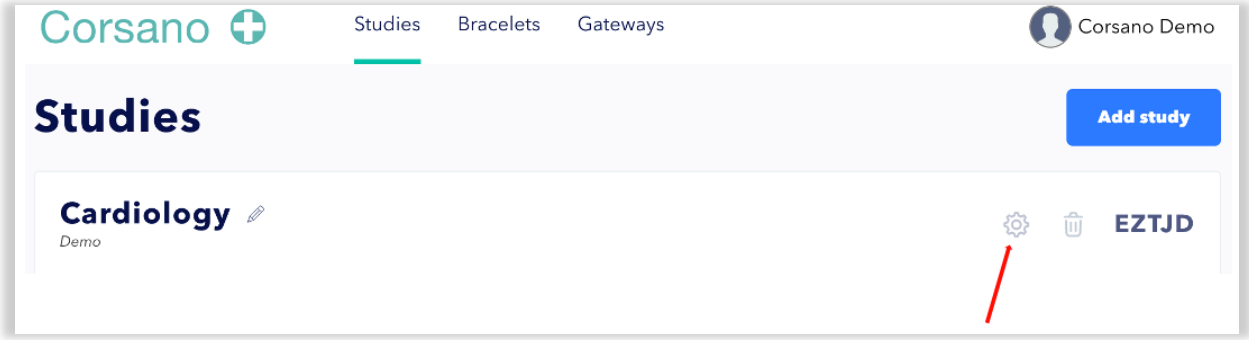
Edit Subject Profile

6. STUDY SETTINGS

The Corsano CardioWatch 287 System enables the Principal Investigator (PI) to adjust Settings for a study:

- Which vital parameters should be recorded
- At what frequency
- If Raw Data should be recorded and stored in cloud
- What information should be shown on Subject App

From the Studies Dashboard in the Study Portal, the PI can adjust Study Settings.



Click Settings

6.1. Selection Bracelet

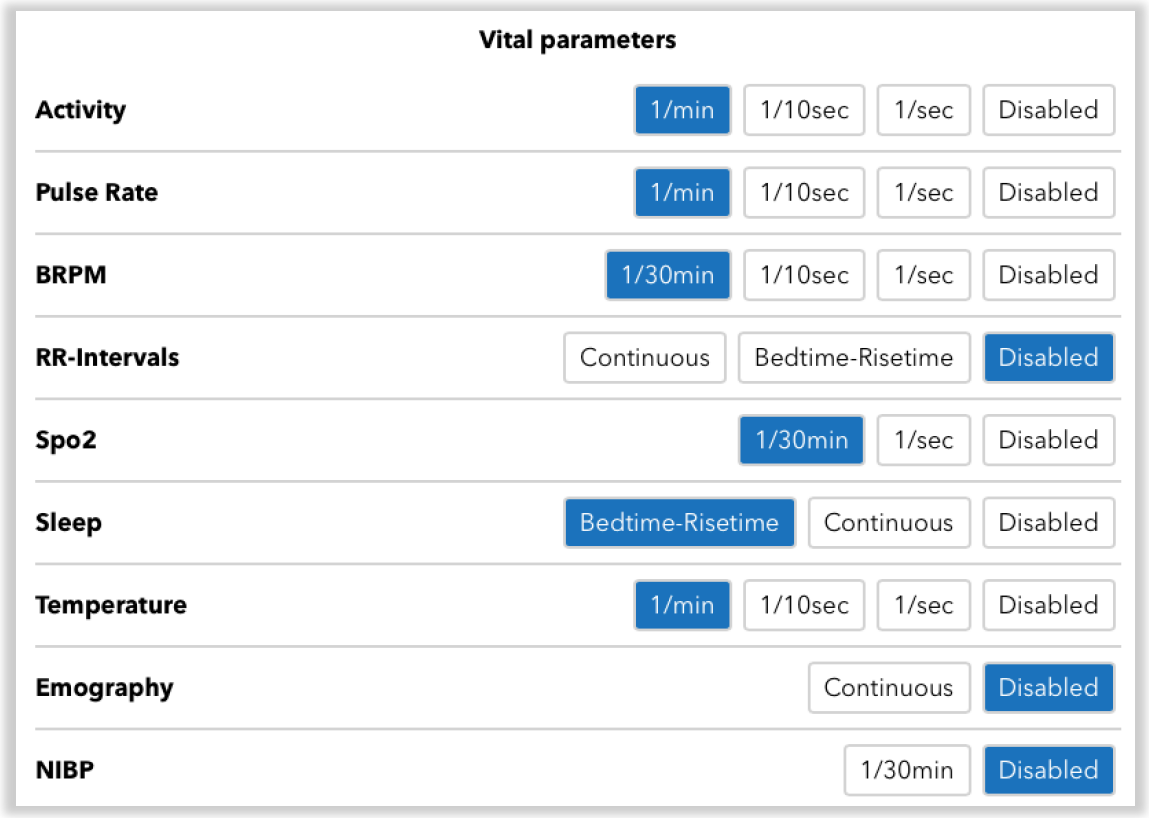
The Study Portal can be used to configure studies for CardioWatch 287-1 and CardioWatch 287-2. Please select 287-1 or 287-2 from the dropdown menu on top of the Settings Page:

Select CardioWatch Bracelet 287-1 or 287-2

NOTE: CardioWatch 287-1 can record only part of vital parameters in comparison with CardioWatch 287-2

6.2. Vital Parameters

The PI can adjust the default selection of vital parameters that should be recorded. The following shows the default settings for CardioWatch 287-2:



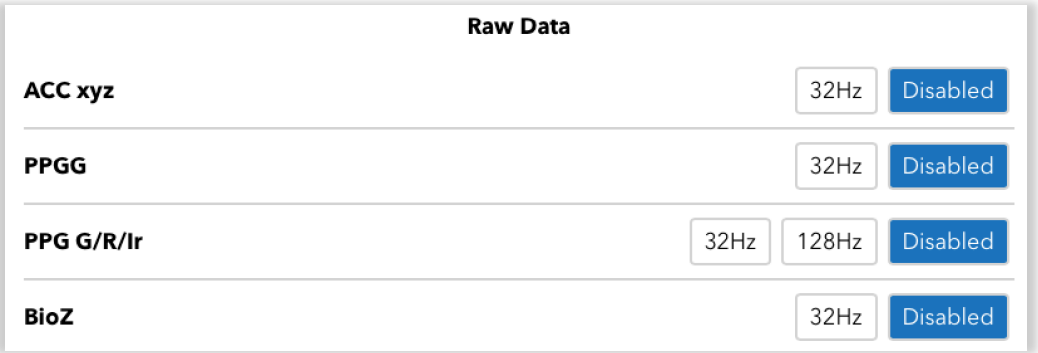
Default Vital Parameter Settings for CardioWatch 287-2

⚠**CAUTION**: Increasing the recording frequency for vital parameters will increase the size of data stored in cloud. Exporting high volume datasets will take longer and may have to be split in multiple downloads. Please consider lowest frequency for your study.

⚠**CAUTION**: Increasing the recording frequency for vital parameters will reduce battery life of the CardioWatch 287 Bracelet. Lower battery life may reduce compliance. Please consider lowest frequency for your study.

6.3. Raw Data

Contrary to other wearable devices, Corsano CardioWatch 287 enables Principal Investigators to record and export Raw Data. By default, recording of Raw Data is disabled.



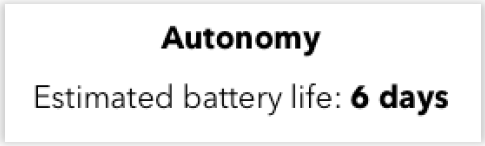
Selection of Raw Data Frequency

⚠ **CAUTION**: Recording of Raw Data will increase the size of data stored in cloud significantly. Exporting high volume datasets will take longer and may have to be split in multiple downloads. Please consider which Raw Data should be recorded for your study.

⚠ **CAUTION**: Recording of Raw Data will reduce battery life of the CardioWatch 287 Bracelet. Lower battery life may reduce compliance. Please consider minimal recording of Raw Data for your study.

6.4. Battery Life

While changing settings for vital parameters and Raw Data, the estimated autonomy of the CardioWatch Bracelet will by dynamically updated:



Autonomy Estimation

The following table shows estimated battery life for different settings:

No Raw Data to Cloud						
	Activity (steps, calories, speed, activity type)	**HR, RR, BRPM (PPGG Intermittent)**	**SpO2 (PPG G/R/Ir Intermittent, 32Hz)**	**Sleep (PPGG Continuous, PPGR/Ir Intermittent)**	**Emography (Continuous)**	**BP (PPG G/R/Ir Intermittent, 128Hz) in development**
1/hour	15	10	7	6	4	5
1/30min	14	9	6	5	4	5
1/min	13	7	4	4	4	N/A
1/sec	12	6	4	N/A	4	N/A
Raw Data Recording						
	ACC	**PPG G Continuous**	**PPG G Continous, PPG R/Ir Intermittent**	**PPG G/R/Ir Continuous**	**BIOZ**	
25Hz	N/A	N/A	N/A	N/A	3	
32Hz	9	5	4	3	N/A	
128Hz	N/A	3	3	2	N/A	

Estimated Battery Life in days of Autonomy

6.5. Corsano App Settings

The PI may decide that the Corsano App on subjects' mobile device should display trending information, for instance Subject Activity Levels (Motion & Steps) Information can be displayed to encourage the subject to be more active.

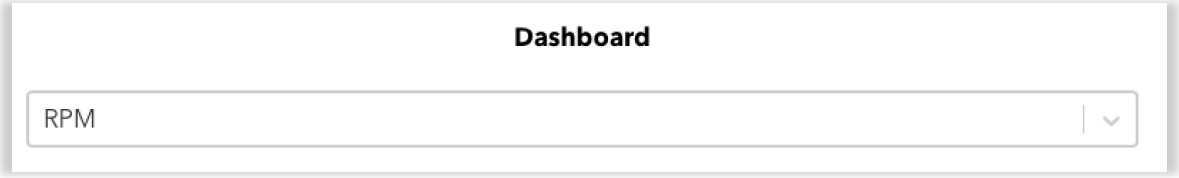
⚠ **CAUTION**: the information provided to the Subject is intended to provide trending data to assist the PI in providing subject motivation. The PI decides which information is shown to the subject based on study protocol.

Such examples may include:

- Activity Levels (Steps) to motivate subject to move sufficiently
- Tracking Temperature and take medicine on instruction of qualified PI in case of fever
- Non-invasive blood pressure spot-measurements data to ensure that subject:
  - has properly done spot-measurements
  - has taken medicine based on instructions of qualified PI
- Spirometry trending to motivate subject exercise to increase in pulmonary capacity
- Pulse rate to motivate the subject to exercise to an increased pulse rate (fat burn)

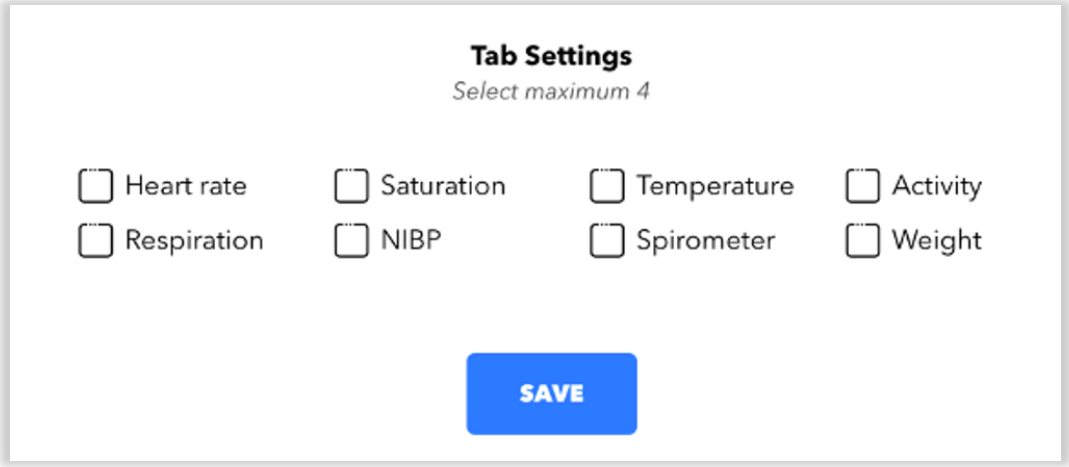
⚠ **CAUTION**: All information displayed in the Corsano App on subjects' mobile device is not for diagnostics use.

Corsano App Dashboard: Corsano designed a number of dashboards for the Corsano App on subjects' mobile device. By default, the dashboard is set to RPM.



Corsano App Dashboard Setting

Corsano App Tabs: The PI decides what information is to be displayed in the Corsano App on subjects' mobile device. Maximum 4 tabs can be selected:



Subject App Tab Settings

By default, no information is displayed on the Corsano App.

⚠ **CAUTION:** Information viewable by the subjects and notifications should be set by the qualified PI after considering the outcomes.

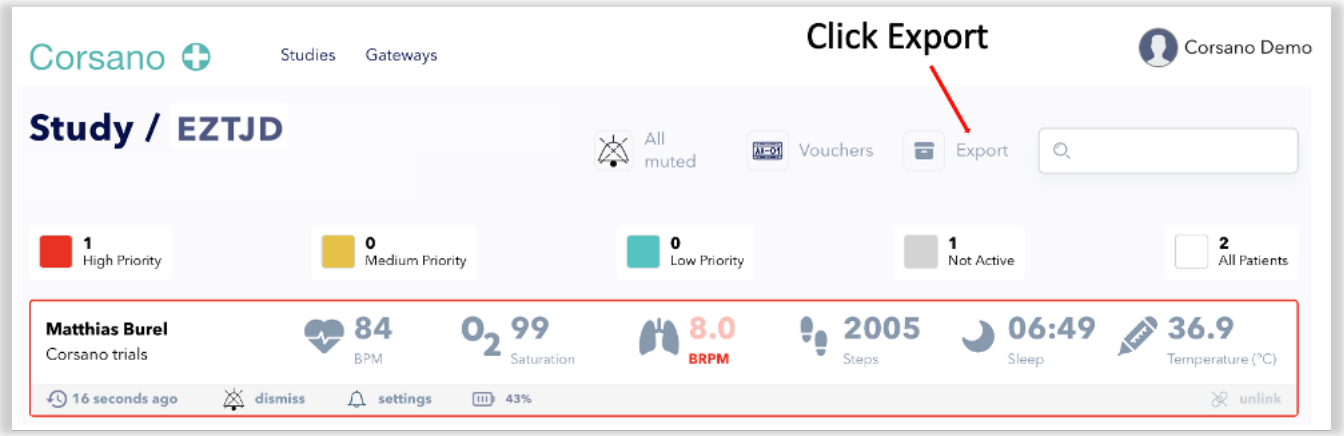
⚠ **CAUTION:** Settings are saved only after the [SAVE] button is pressed.

7. EXPORT DATA

Via the Study Portal a PI can export data for a study or individual subjects.

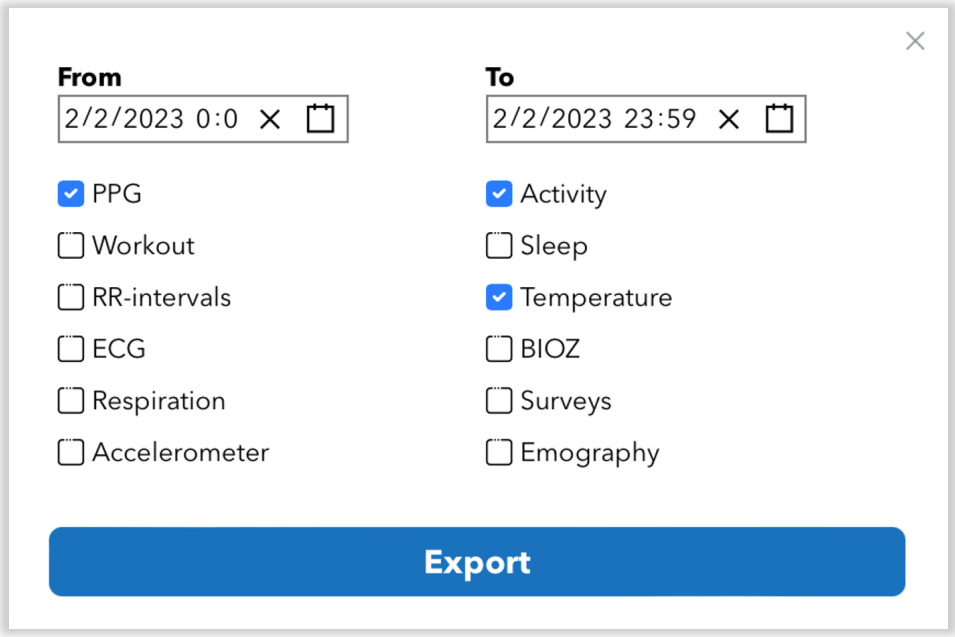
7.1. For a Study

Data can be exported for multiple days for all subjects from the Study Dashboard:



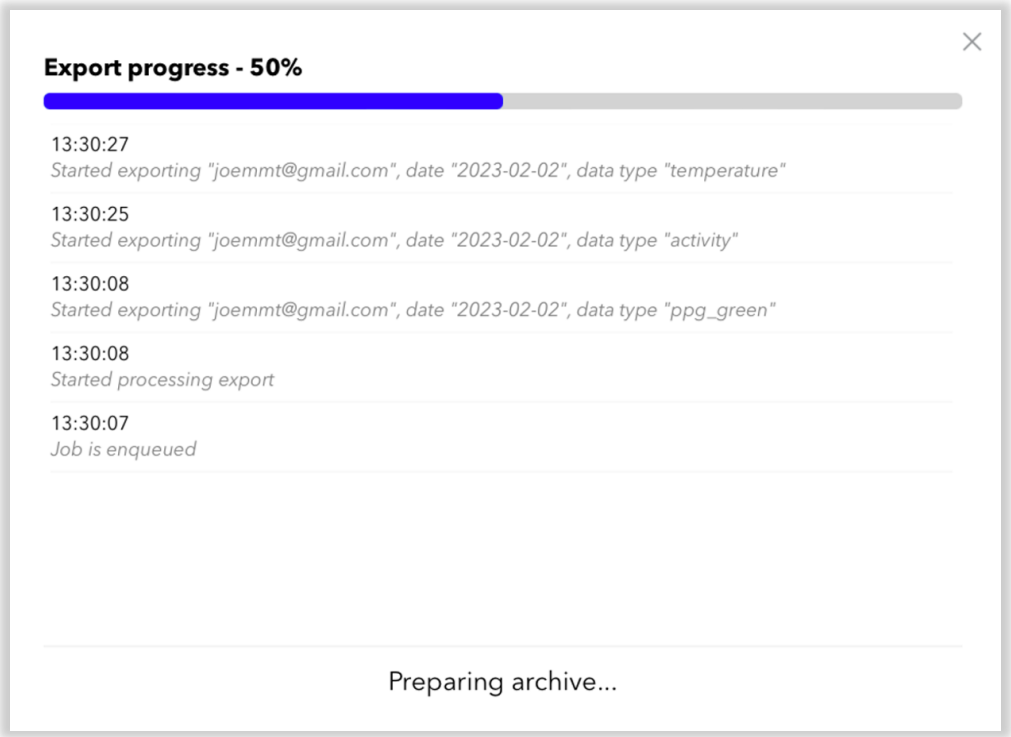
Export data for multiple subjects

Please select which vital parameters should be exported:



Select Period and Vital Parameters to be exported

The system will start preparing the archive after the [EXPORT] Button is pressed:



Archiving Export Request

Upon completion you can download the archive and save on your computer:

Archive is ready for download

Depending on the size of the dataset, the waiting time can vary from seconds to minutes.

⚠ **CAUTION:** For studies with many subjects, selection of a longer period may create too large data files. Please choose shorter period.

If you are exporting PPG or BIOZ data, we recommend setting the range up to 24 hours. If you are exporting data that does not contain PPG or BIOZ, you may set the range up to 3 days.

The size of export can vary from kilobytes to gigabytes if unarchived.

7.2. For Individual Subjects

Data can also be exported for an individual subject via the Subject Portfolio page:

Data Export for Individual Subject

To download ECG records data please click on button “export .csv” in the list of ECG records on the Pulse Rate tab.

Export of ECG measurements

8. DATA

CardioWatch 287 devices measure summaries for vital parameters and raw data.

8.1. Summaries

Summaries contain daily summary of the vital parameter and list to individual data slots.

Summary	Description	Comment
Heart Rate summary	Daily average Daily max HR Daily resting HR Active time (in minutes) Time in HR zones Max HR (>90% maximum CF) Performance zone (>80% max CF) Endurance zone (>80% max CF) Fat Burn zone (>70% max CF) Warm Up zone (>60% max CF) Rest zone (>50% max CF) Start time Stop time List of slots	
Heart Rate slots	Timestamp Date HR in BPM HR Quality Index (4=highest quality, 0=bad quality)	
Steps summary	Step count Distance in m Step calories in kcal Percentage of steps goal Workout count Start time Stop time List of slots	
Steps slots	Timestamp Date Step count Energy expenditure in kcal Speed in m/s Activity type 0=UNSPECIFIED 1=OTHER 2=WALK 4=RUN 6=CYCLE 7=REST	

Respiration summary	Average Start time Stop time List of slots	
Respiration slots	Timestamp Date Respiration rate Quality index (4=highest quality, 0=bad quality)	
Sleep summary 1/day	Duration in minutes Percentage of sleep goal Sleep need duration in minutes Awake time in minutes Time in REM stage (in minutes) Time in light sleep (in minutes) Times in deep sleep (in minutes) Performance (0-100% based on sleep goal and sleep need) Tranquility (number of wake-ups) Consistency (0-100% based on last 7 days) Date List of slots	
Sleep slots	Sleep stage 0=NONE 1=AWAKE 2=REM 3=LIGHT 4=DEEP	1 min slots
Temperature summary	Average Temperature 1 Average Temperature 2 Start time Stop time List of slots	
Temperature slot	Timestamp Date Temperature 1 Temperature 2	CW287-1: Only Temperature 1=empty field Temperature 2=skin temperature during the night CW287-2: Temperature 1=Core Body Temperature (day and night) Temperature 2=skin temperature during the night

Saturation summary	Average Start time Stop time List of slots	Only CW287-2B
Saturation slots	Timestamp Date Quality index (4=highest quality, 0=bad quality)	Only CW287-2B
Stress summary	Timestamp Average level of skin conductance in 100pS units Start time Stop time	Only CW287-2B
Stress slot	Timestamp Cognitive zone (CZ) 0=UNDIFINED 1=UNDER STIMULATED 2=NORMAL 3=OVER STIMULATED Predictive CZ (next predicted cognitive zone) Predictive CZ Transition Time (in minutes) CZ Hour (CZ in 1h) Cortisol contribution CZ Quality Index (4=highest quality, 0=bad quality) Stress level skin conductance Stress level skin conductance Quality Index (4=highest quality, 0=bad quality)	Only CW287-2B (more information available on demand)
Wearing	Timestamp Wearing detection status	0: Not wearing 1: UNUSED 2: Cannot determine 3: UNUSED 4: Wearing

8.2. Raw Data

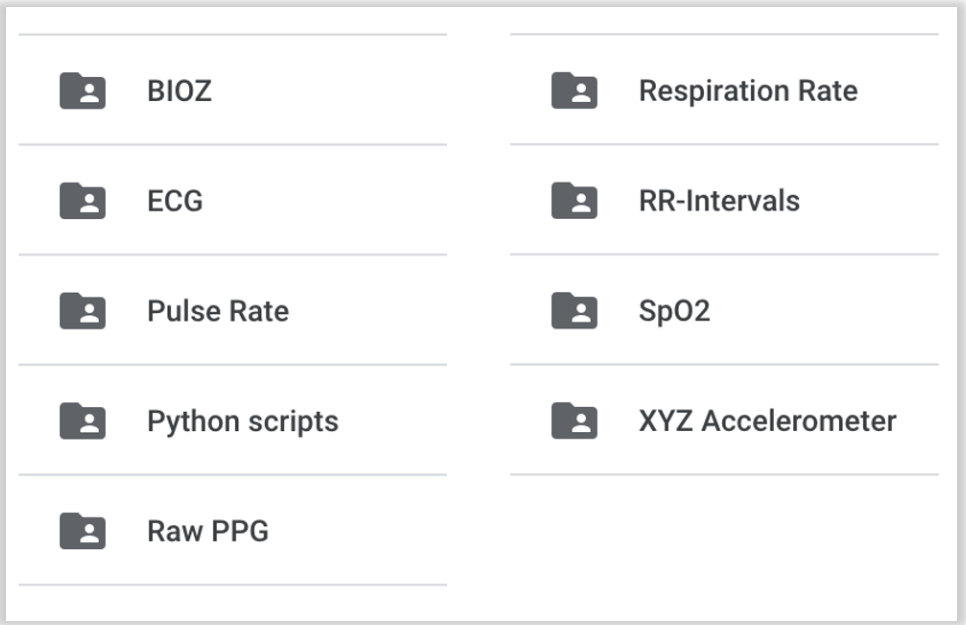
Raw data are time series of data, each record is marked with a timestamp (UNIX timestamp in MS since Jan 1st, 1970) and full string date with ISO format that is used to keep track of the subject's local time zone.

Raw Data	Description	Comments
ACCx, ACCy, ACCz	Accelerometer data (X, Y, Z) Range: -8g to 8g Value: 0.015625 g/adc count	CW287-1: 25Hz CW287-2: 32Hz

ACC	Norm_of_d_acc[t] = sqrt(d_accX[t] * d_accX[t] + d_accY[t] * d_accY[t] + d_accZ[t] * d_accZ[t]);
	
	Where :
	d_accX[t] = acc_x[t]- acc_x[t-40ms];
	d_accY[t] = acc_y[t]- acc_y[t-40ms];
	d_accZ[t]= acc_z[t]- acc_z[t-40ms];
		CW287-1 only

CRC	CRC code for the frame	
PPG	PPG data	CW287-1: 25Hz CW287-2: 32Hz/128Hz
HRV	Timestamp RR interval in ms	
BIOZ	Timestamp Skin conductance in 100pS units	Only CW287-2: 32Hz

Please see this link for examples of datasets recorded with CardioWatch 287-2.

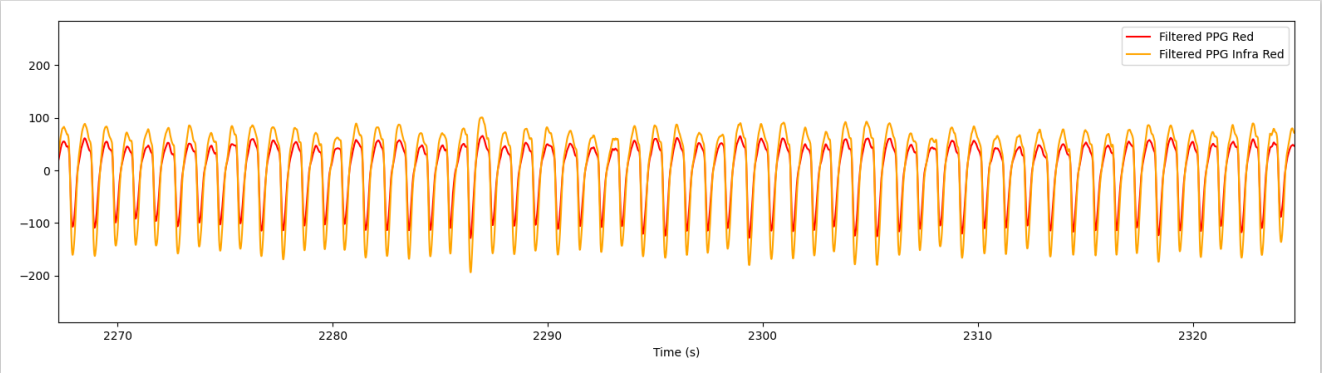


Examples of Data Files recorded with CardioWatch 287-2

8.3. Data Processing Tools

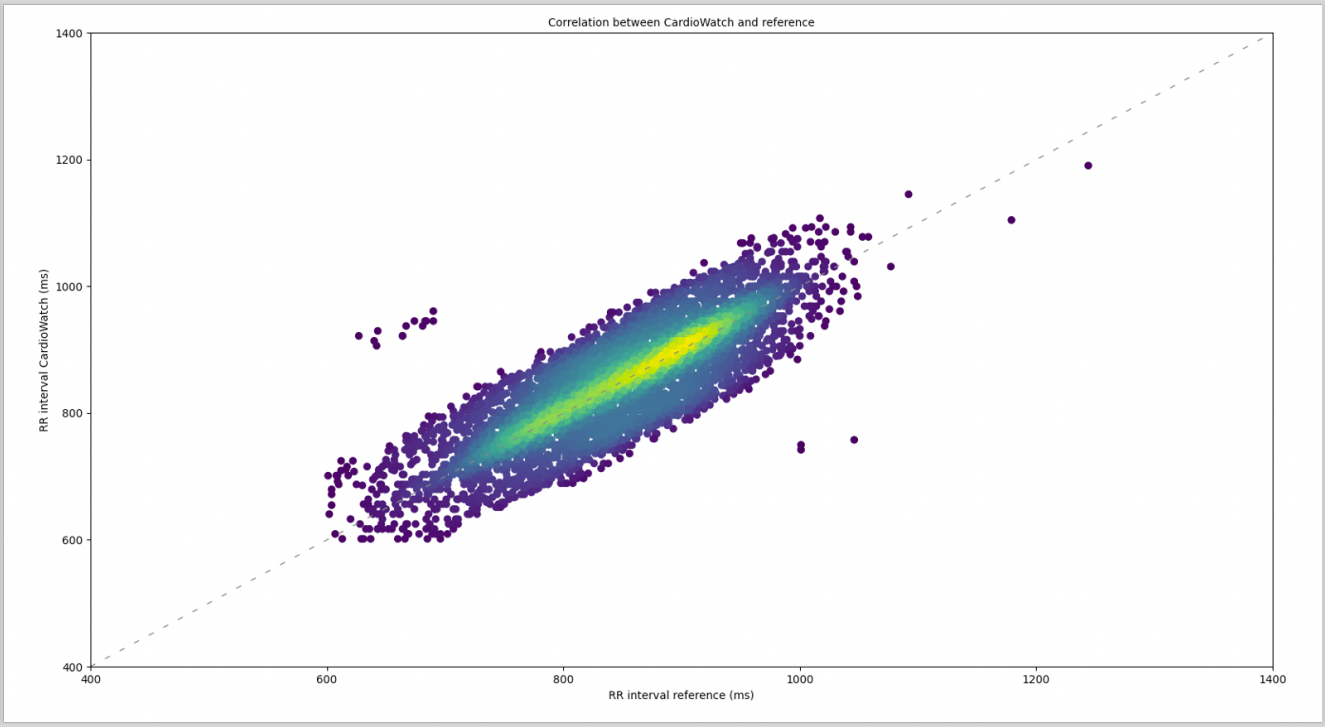
Please contact Corsano for Phyton scripts to plot Filtered PPG Curves, Correlation and Bland-Altman plots.

Here is an example of Filtered PPG Red and PPG iR to determine SpO2:



Example Filtered PPG Red and PPG iR

And an example of Correlation PPG RR-Intervals at 128Hz versus ECG Reference Device measured while during the day under motion:



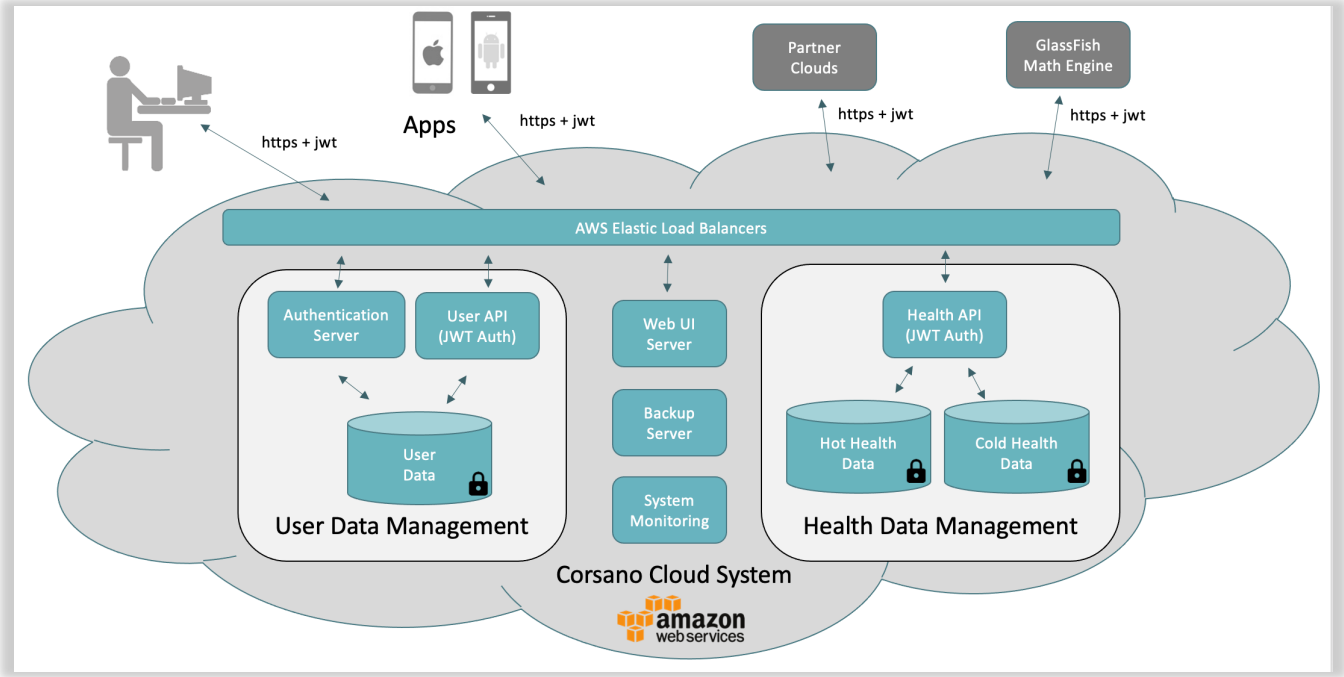
Example Correlation PPG RR-Intervals at 128Hz verses ECG Reference Device

9. API

Corsano offers a REST API to access data recorded on its secure cloud. Use of the REST API assumes a working knowledge of APIs and their implementation.

9.1. Corsano Cloud System

The CardioWatch 287 Cloud has been implemented on AWS. User Data and Health Data are encrypted and fully separated.



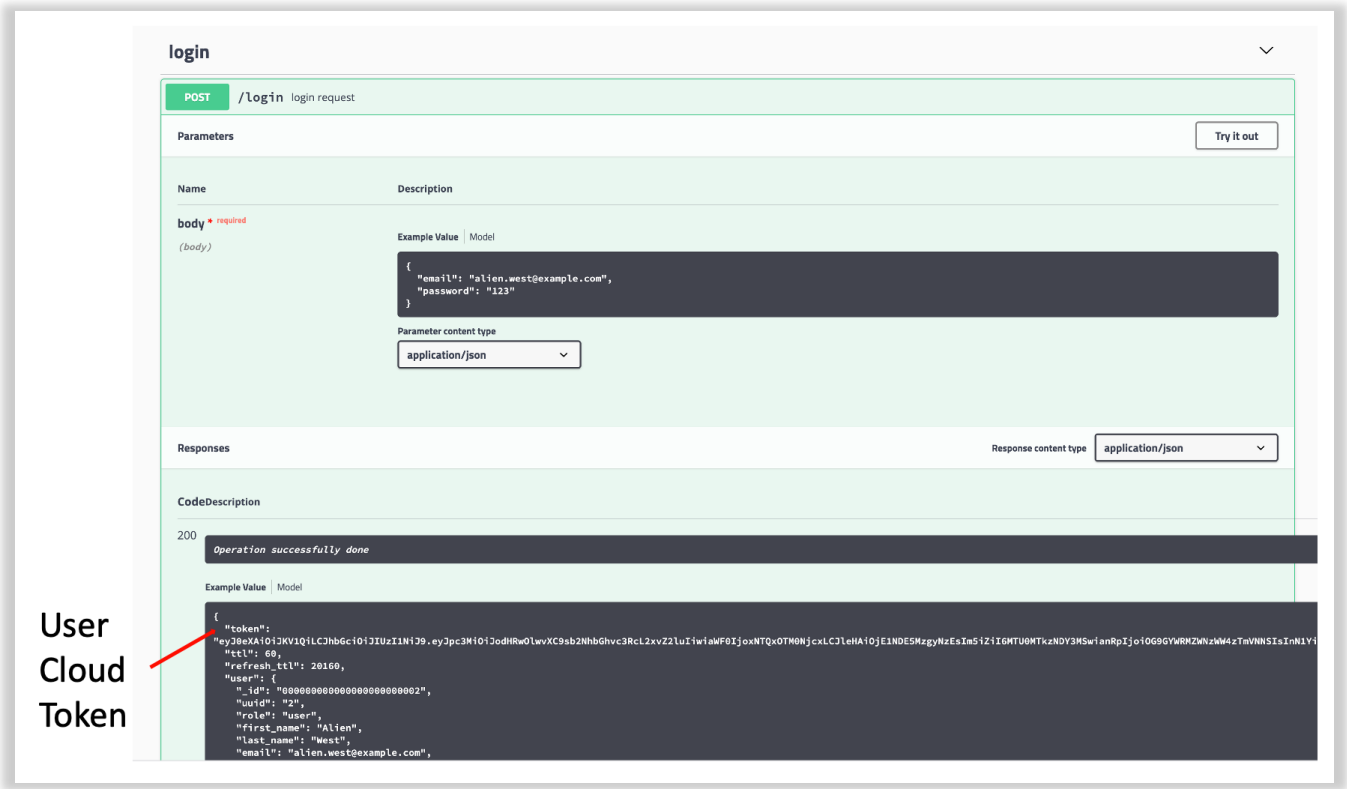
Corsano CardioWatch 287 Cloud System

9.2. Users Cloud

Details can be found on https://api.users.cloud.corsano.com

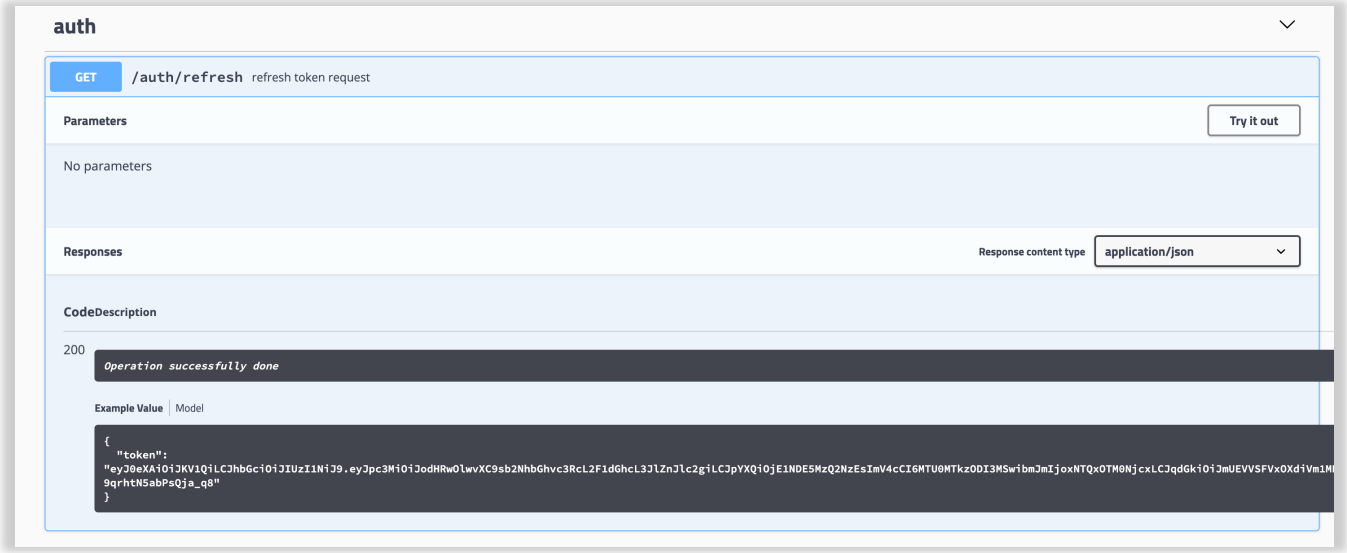
First step is to create a Users Cloud Token. With same email and password, you can get an access token, see LOGIN request in the API documentation.

NOTE: You will have access to data for only one subject. To access data for multiple subjects, please contact Corsano.



Create User Cloud Token

⚠**CAUTION:** Token must be regularly refreshed. Please make sure to REFRESH the Token every 30 minutes with this request.

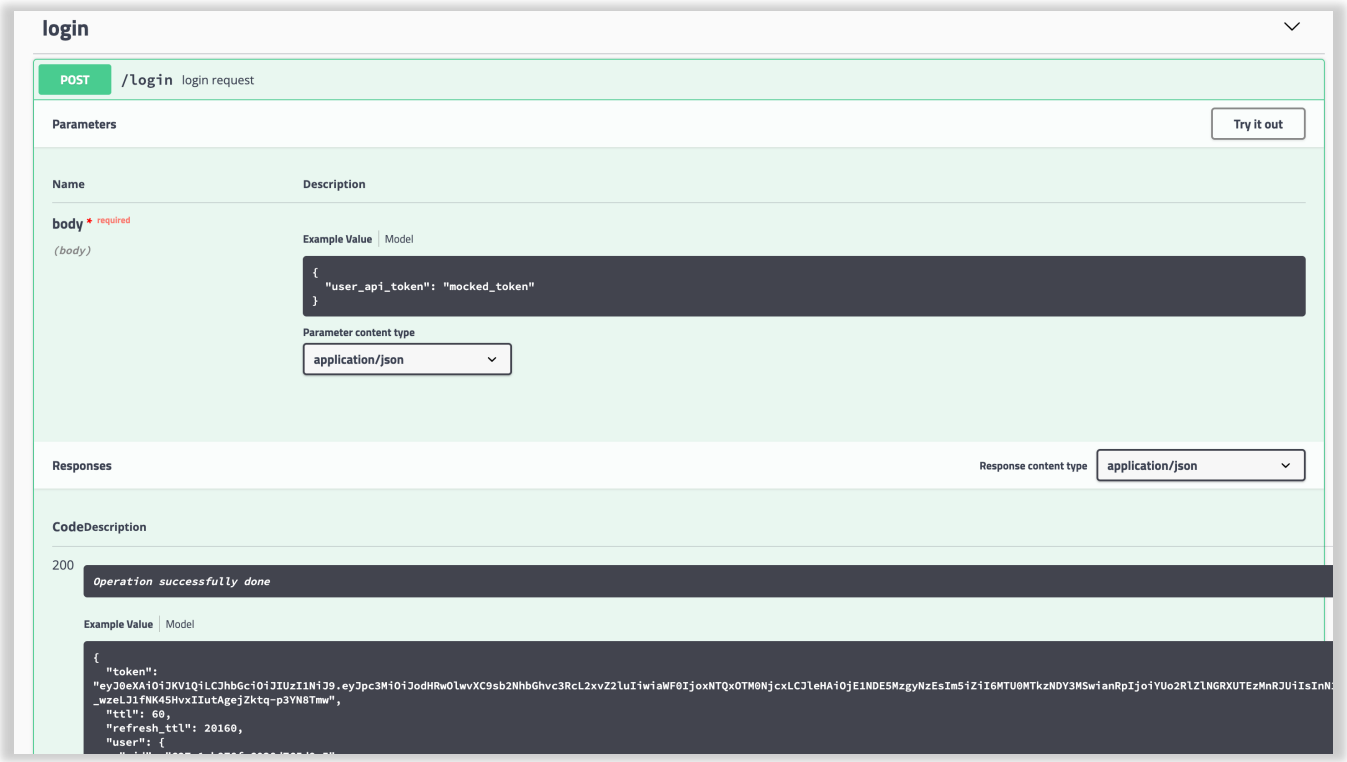


Refresh User Cloud Token

9.3. Health Cloud

Details can be found on https://api.health.cloud.corsano.com

You need to exchange the User Cloud Token to Health Cloud Token by making LOGIN request to Health Cloud.



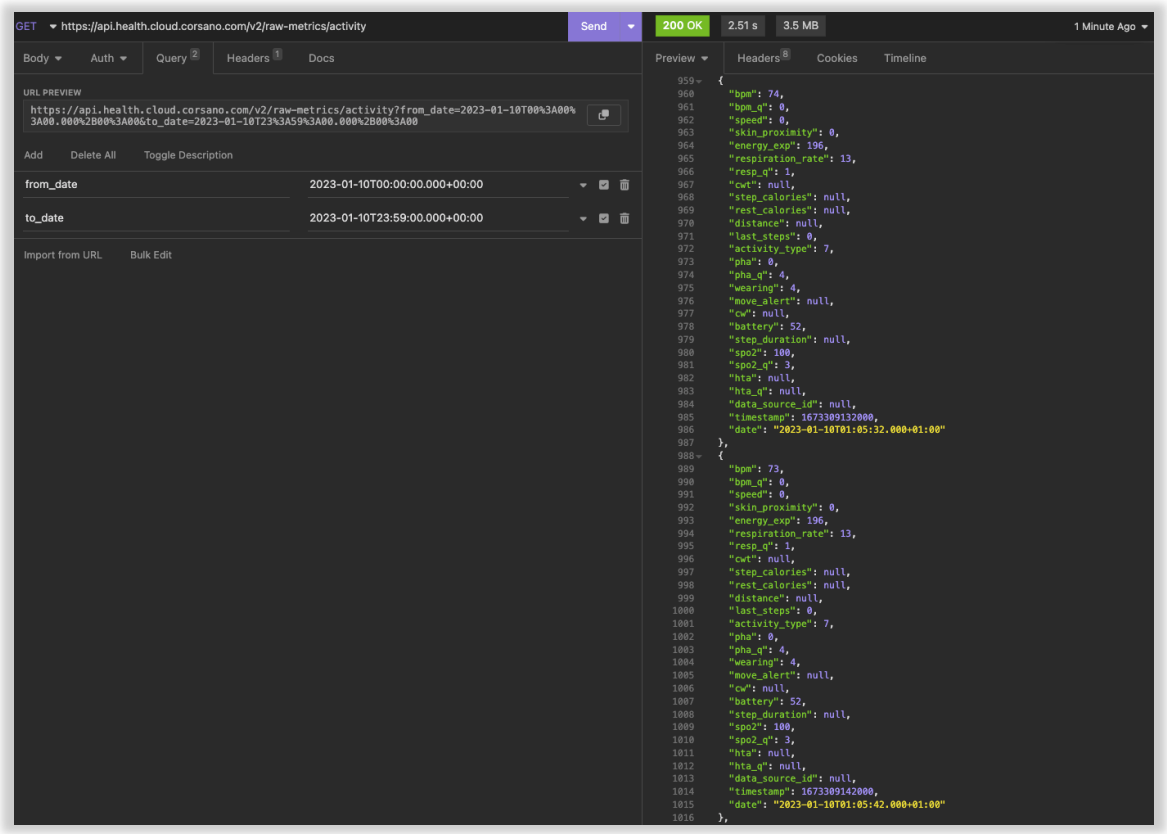
Get Health Cloud Token

⚠ **CAUTION:** Please do not forget to REFRESH also this Health Cloud Token

Once you obtained a Health Cloud access token you can retrieve the data.

Example of retrieving data of activity data of the patient:

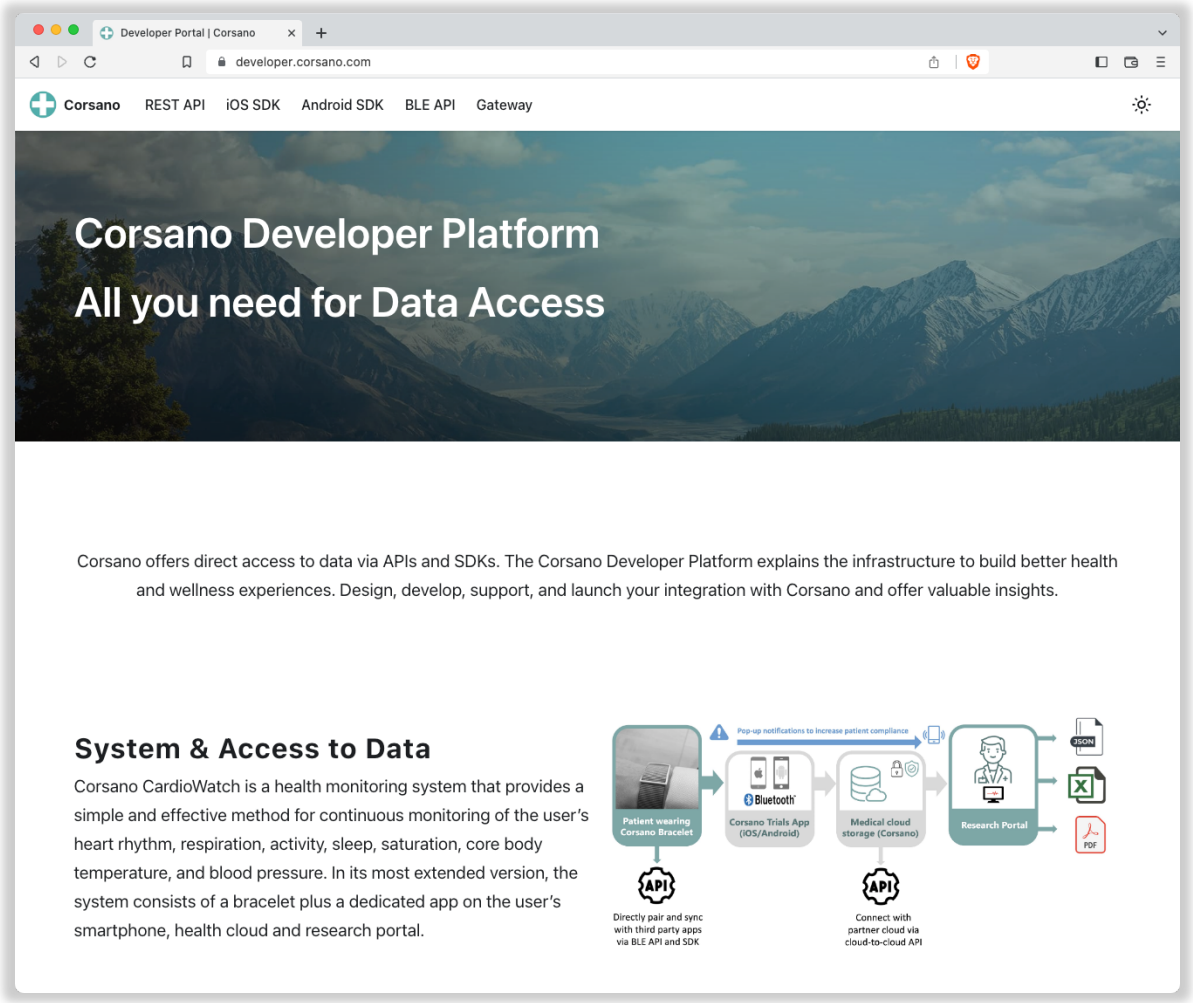
```
curl --request GET \
  --url 'https://api.health.cloud.corsano.com/v2/raw-metrics/activity?from_date=2023-01-10T00%3A00%3A00.000%2B00%3A00&to_date=2023-01-10T23%3A59%3A00.000%2B00%3A00' \
  --header 'Authorization: Bearer eyJ0eXAiOiJKV1QiLCJhbGciOiJIUzI1NiJ9.eyJpc3MiOiJodHRwOlwvXC9hcGkuaGVhbHRoLmNsb3VkLm1tdC5jaFwvbG9naW4iLCJpYXQiOjE2NzU2Mjc2NjUsImV4cCI6MTY3NTYzMTI2NSwibmJmIjoxNjc1NjI3NjY1LCJqdGkiOiJFNlU3eGZ1dm9UeGptcGdqIiwic3ViIjoiNjA0OTJjZTk4YTI2MGJlYjFjZjA1YTQ3IiwicHJ2IjoiMjNiZDVjODk0OWY2MDBhZGIzOWU3MDFjNDAwODcyZGI3YTU5NzZmNyJ9.O9GJAGvFxlpz37flE3BJdMP-ReiNdf02i4K9dR5niGM'
```



Example of getting activity data of the patient using REST API

9.4. Developer Knowledge Base

Please see https://developer.corsano.com for extensive information on Corsano's API and SDK functionality.



Corsano Developer Portal

The Developer Portal has 5 sections:

- REST API
- iOS SDK
- Android SDK
- BLE API
- Gateway

10. CYBERSECURITY

10.1. Information Security Management System

Corsano Health has established an Information Security Management System (“ISMS”) in accordance with ISO/IEC 27001 (“ISO 27001”) that governs the processes required to protect company and information assets. Corsano Health utilizes the ISO 27001 Information Security (“InfoSec”) frameworks in order to identify and maintain the assets, technologies, and processes needed to protect customer information and to help ensure the confidentiality, integrity, availability, and privacy of customer data and supporting services.

To enable this, Corsano Health:

1. Aligns its InfoSec policies and procedures to the global industry standard ISO 27001
2. Achieves a robust InfoSec framework for the efficient functioning of the organization

While Corsano Health has taken significant steps to protect the CardioWatch 287 System from cyberattacks, the user has a crucial role in maintaining cybersecurity. The guidelines in this section must be followed.

The Corsano Bracelet communicates with the Corsano App through a secure Bluetooth 5.0 communication link with a state-of-the-art encryption layer. The Corsano App transmits the data to the Corsano Cloud. Communications between the Corsano Bracelet, App and Cloud are encrypted to an industry-standard.

The Corsano App can be installed on an iOS device running iOS version 13 or greater, or an Android device running Android version 8 (Oreo) or 9 (Pie). As Apple review every application before it is allowed on the Apple App Store, the iPhone is very resilient to cyberattacks. The Google Play store reviews applications for the Android platform.
The Corsano Study Portal is accessible via the Safari or Google Chrome web browser. All communications between the Study Portal and the Corsano Cloud are encrypted to an industry-standard, using TLS1.2+.

10.2. About password policies, password expiration and auto-logout

A combination of username and password are used to control access to the Web Poertal and Corsano App. The App requires that the user creates a strong password (More than eight characters, containing letters, digits, capital and small letters, at least one special character). It is the responsibility of the user to apply the appropriate password policies e.g. password complexity, renewal intervals.

Follow these general recommendations on password:

- Use a minimum password length of 8 characters
- Include lowercase and uppercase alphabetic characters, numbers and symbols
- Generate passwords randomly where feasible
- Passwords should be renewed after 90 days.

10.3. About periodical software updates and patches

The Corsano App should be updated as soon as a new version becomes available. When a new version does become available, the Apple App Store in the case of iOS or the Google Play Store in the case of Android, will automatically update the app in-place. When accessing the Corsano Study Portal via the web interface, the user will always have access to the most up to date version.

10.4. Dealing with a lost or stolen Corsano Bracelet

In case a Corsano Bracelet is lost or stolen, please notify Corsano Health with the Serial Number of the bracelet.

10.5. General Guidelines for Security

1. The computer running the Study Portal must have up-to-date anti-malware software installed
2. The computer running the Study Portal must have screen locking and password protection
3. Any mobile device with the Corsano App installed must also have a device passcode set
4. You should never disclose your Corsano username or password. No Corsano Health staff will ever ask you for these details
5. You should never write your Corsano username or password down
6. You should never provide an unauthorized user access to the Corsano App
7. You should never leave the Corsano App and Study Portal logged in and unattended. Please log out when you have finished using the system
8. You should never disclose protected health information within a support message to Corsano Health. This includes details like a subject's name or date of birth.

11. WARRANTY

Corsano Health warrants that components within its products will be free from defects in workmanship and materials for a period of one year from the date of purchase.

This warranty does not cover consumable items such as, but not limited to, straps.

Corsano Health shall not be liable for any incidental, special, or consequential loss, damage, or expense directly or indirectly arising from the use of its products. Liability under this warranty and the buyer's exclusive remedy under this warranty is limited to servicing or replacing the affected products, at Corsano Health's option, at the factory or at an authorized distributor, for any product which shall under normal use and service appear to Corsano Health to have been defective in material or workmanship.

No agent, employee, or representative of Corsano Health has any authority to bind Corsano Health to any affirmation, representation, or warranty concerning its products, and any affirmation, representation or warranty made by any agent, employee, or representative shall not be enforceable by buyer or user.

THIS WARRANTY IS EXPRESSLY IN LIEU OF, AND CORSANO HEALTH EXPRESSLY DISCLAIMS, ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, NON-INFRINGEMENT, OR FITNESS FOR A PARTICULAR PURPOSE, AND OF ANY OTHER OBLIGATION ON THE PART OF CORSANO HEALTH.

Damage to any product or parts through misuse, neglect, accident, or by affixing any non-standard accessory attachments, or by any customer modification voids this warranty.

Corsano Health makes no warranty whatsoever in regard to trade accessories, such being subject to the warranty of their respective manufacturers.

A condition of this warranty is that the equipment or accessories which are claimed to be defective be returned when authorized, freight prepaid to Corsano Health, Wilhelmina van Pruisenweg 35, 2595 AN The Hague, The Netherlands or its authorized representative. Corsano Health shall not have any responsibility in the event of loss or damage in transit.

Corsano Health's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Corsano Health.

This warranty shall not extend to a) malfunction or damage caused by improper use or man-made failure; b) malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people; c) malfunction or damage caused by unstable or out-of-range power input; d) damage or wear and tear of straps.

12. CORSANO CONTACT INFORMATION

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2595 AN The Hague
The Netherlands

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support@corsano.com